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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/069,906

02/22/2002

Setsuko Ueda

F-7333

5913

28107

7590

10/16/2003

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 10/16/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,906

Applicant(s)

UEDA ET AL

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1-7 under 35 USC 112, second paragraph is made moot by the cancellation of the instant claims.

Claim Rejections - 35 USC § 102

3. The rejection of claims 1-5 and 7 under 35 USC 102(b) over Tamarkin ('669) is made moot by the cancellation of the instant claims.
4. The rejection of claims 1-5 and 7 under 35 USC 102(b) over Reeve et al. (EP 196,632) is made moot by the cancellation of the instant claims.
5. Claims 8, 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Oota (JP 55,035,025).

Oota teaches a composition containing almost equal amounts of polyethylene glycol of 3,000-5,000 molecular weight and 300-500 molecular weight, up to about 30 wt%, based on the polyethylene glycols, of salicylic acid and about 10 wt%, based on the above total amount, of ethanol useful as a dermatophytosis remedy (see the entire

Art Unit: 1616

article; especially Abstract). The composition taught by the reference is encompassed by the instant claims.

6. Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Tamarkin ('669).

Tamarkin teaches a composition consisting of azelaic acid, salicylic acid and polyethylene glycol. The composition taught by the reference is encompassed by the instant claims.

7. Claims 8, 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Seabra (GB 754,867).

Seabra teaches a composition comprising 24 parts of salicylic acid, 8 parts by weight of calcium carbonate and 160 parts by weight of polyethylene glycol. The composition taught by the reference is encompassed by the instant claims.

8. Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Reeve et al. (EP 196,632).

Reeve teaches a gel comprising a mixture of organic polysaccharide and polyethylene glycol useful in the delivery of drugs to the skin. The reference teaches the delivery of drugs such as salicylic acid (see the entire article, especially page 3, lines 22-28; examples 1-3, 5 and 6). The composition taught by the reference is encompassed by the instant claim.

Claim Rejections - 35 USC § 103

9. The rejection of claims 1-7 under 35 USC 103(a) over Reeve et al. (EP 196,632) and Tamarkin ('669) in combination is made moot by the cancellation of the instant claims.

10. Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeve et al. (EP 196,632) in view of Tamarkin ('669).

Reeve teaches a gel comprising mixture of organic polysaccharide and polyethylene glycol useful in the delivery of drugs to the skin. The reference teaches the delivery of drugs such as salicylic acid (see the entire article, especially page 3, lines 22-28; examples 1-3, 5 and 6).

The instant claims differ from the reference by reciting compounds not exemplified by the reference. However, salicylic acid and resorcinol are known anti-acne/keratolytic agents (see Tamarkin, '669, col. 5, line 57 – col. 6, line 27). Thus, it would have been obvious to the skilled artisan in the art at the time of the invention to substitute any anti-acne/keratolytic agent in the composition taught by Reeve with the reasonable expectation of obtaining a composition for topical application to the skin as taught by Reeve. The motivation would be based on the desire to formulate other anti-acne/keratolytic agents in a composition useful for topical application.

Other Matters

11. Applicant's arguments that (a) composition (2) of Example 7 of Tamarkin is for comparison only and is stated to have an irritation reaction when applied to the skin and (b) the function of the polysaccharide gum in the compositions of Reeve et al. is entirely different from that of applicants' chemically peeling agent are noted. However, the phrase "consisting essentially of" does not eliminate azelaic acid or the polysaccharide gum from the claimed invention and, thus, the claimed composition would encompass the prior art compositions.

The examiner notes that the phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention (MPEP § 2111.03). Applicant has not provided any factual evidence showing that any of the components of the prior art compositions changes the characteristics of applicant's invention. In the absence of such a showing, the claimed composition is not patentable over the compositions of the prior art.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1616

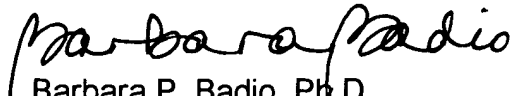
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308- 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
October 14, 2003